

RECEIVED
CENTRAL FAX CENTER

DEC 04 2006

PATENT

Appl. No. 09/844,281
Amdt. dated December 4, 2006
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1645

REMARKS/ARGUMENTS

Claims 16-19, 44, 50-54, and 56-65 have been canceled without prejudice for re-presentation in a continuing application.

Claim 68 has been revised to correct a typographical error. Applicants thank Examiner Graser for recognizing that claim 68 should depend from claim 66.

No new matter has been introduced, and entry of the above revised claims is respectfully requested.

Alleged issues under 35 U.S.C. §112, Second Paragraph

Pending claims 66-85 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for reciting "relative to". Applicants have carefully reviewed this rejection and respectfully traverse because no *prima facie* case has been presented. Applicants submit that the artisan of ordinary skill would interpret the claim language in its context and find no ambiguity or indefiniteness in the scope of the claimed subject matter.

As an initial matter, Applicants point out that the language of the claims must be read in the context in which they are presented. In fact, MPEP 2173.02 includes the guidance to "consider the claim as a whole". With this in mind, the relevant portion of independent claim 66, 69, and 79 is

"(b) specifically binds spores or vegetative cells of *B. anthracis* relative to the spores or vegetative cells of *B. thuringiensis*, *B. cereus*, *B. globigii*, and *B. licheniformis*." (emphasis in bold added)

As evident from the above, the term "relative to" is not used in a vacuum or in an ambiguous fashion. Instead, it is used in the context of identifying a feature of the monoclonal antibody, or fragment thereof, recited in claims 66, 69 and 79. That feature is the binding activity of the antibody, or fragment, where it "specifically binds" a first group of entities (spores

Appl. No. 09/844,281
Amdt. dated December 4, 2006
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1645

PATENT

or vegetative cells of *B. anthracis* "relative to" a second group of entities (the spores or vegetative cells of *B. thuringiensis*, *B. cereus*, *B. globigii*, and *B. licheniformis*).

The statement of the rejection, however, fails to consider this overall context of the claims and instead misplaces its focus solely on the term "relative to" without consideration of how a practitioner of ordinary skill in the antibody art would understand the language as used in the claim. Applicants respectfully point out that a skilled person would understand that a monoclonal antibody, or fragment thereof, is considered to have some level of binding specificity. Additionally, a skilled person would understand that a level of binding specificity is "relative" in that the antibody would bind one or more entities while not binding one or more others by comparison.

Therefore, a skilled person would readily understand that a monoclonal antibody, or fragment thereof, that "specifically binds" a first group of entities "relative to" a second group of entities is an acceptable means of describing the binding activity of the antibody or fragment via use of comparative language. Accordingly, and contrary to the conclusory statement at the end of the statement of this rejection, the above quoted language from the claims would clearly convey the meaning that the antibodies, or fragments thereof, must specifically bind spores or vegetative cells of *B. anthracis* "relative to" the spores or vegetative cells of *B. thuringiensis*, *B. cereus*, *B. globigii*, and *B. licheniformis*.

In light of the foregoing, Applicants respectfully submit that this rejection is misplaced and may be properly withdrawn.

The same claims 66-85 have also been rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for "mere recitation of a name, i.e., EA1 to describe the invention". Applicants again respectfully traverse because no *prima facie* case has been presented. Applicants submit that the artisan of ordinary skill in the relevant field of technology. That skilled artisan would understand the claims as setting forth the unambiguous identity of the EA1 polypeptide as that of *B. anthracis*.

Appl. No. 09/844,281
Amdt. dated December 4, 2006
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1645

PATENT

As an initial matter, Applicants point out that this rejection appears misplaced at least with respect to claim 73, which recites "SEQ ID NO:1 or an antigenic portion thereof." A simple review of the application clearly shows that SEQ ID NO:1 corresponds to the EA1 polypeptide. Accordingly, where is the factual basis to support the allegation that the skilled person would not recognize the meaning of "EA1 polypeptide" in claim 73?

Additionally, Applicants point out that the language at issue is "EA1 polypeptide of *B. anthracis*". This language is used in the context of identifying a feature of the monoclonal antibody, or fragment thereof, recited in claims 66, 69 and 79. The feature is the binding activity of the antibody, or fragment, to a particular *B. anthracis* polypeptide known as EA1.

But with respect to the remaining claims, the instant statement of the rejection asserts that recitation of the name of the protein "does not adequately define the claimed antibody. The antigen to which the antibody binds is a critical limitation."

Therefore, it appears that the basis of this rejection is that the skilled person would not understand what is meant by the EA1 polypeptide of *B. anthracis*. This allegedly would then lead to the inability to understand what is meant by an antibody that binds this polypeptide.

But factually, this is clearly wrong. Applicants have point out the understanding of EA1 polypeptide of *B. anthracis* in the art as indicated by the previously provided documents. The documents include that of Ezzell Jr. et al., which was applied in the Office Action mailed October 3, 2006 as allegedly disclosing antibodies against the EA1 polypeptide of *B. anthracis*. But Ezzell Jr. et al. clearly indicate that the meaning of EA1 protein was known and recognized in the field (see page 349, right column, first full paragraph). This understanding is supported by the Phillips et al. (abstract only) and Farchaus et al. documents as well as deposited sequences in the field. Applicants respectfully submit that this supports their contention that the term EA1 polypeptide of *B. anthracis* is understood as referring to particular subject matter recognized in the field. Additionally, Applicants point out that the term is being used in a manner consistent with that by others in the relevant field, such as the authors described above.

Appl. No. 09/844,281

PATENT

Amdt. dated December 4, 2006

Amendment under 37 CFR 1.116 Expedited Procedure

Examining Group 1645

In response, the statement of the rejection does not provide any factual basis to refute this evidence of knowledge in the field, and so knowledge of the skilled artisan. Instead, the statement goes on (see page 4) to incorrectly require the description of EA1 epitopes that are specific to *B. anthracis* in order to convey the meaning of the antibodies. But Applicants again point to the fact that the skilled artisan would recognize the language at issue as simply referring to the *B. anthracis* polypeptide known in the art as EA1. That polypeptide would include the epitopes that are specific to *B. anthracis* and so no specific recitation of the epitopes is needed to provide definiteness in the claims.

In light of the foregoing, and contrary to the instant rejection, there is no ambiguity in the identity of the "EA1 polypeptide of *B. anthracis*" or the featured antibodies. Accordingly, Applicants respectfully submit that this rejection may be properly withdrawn.

Claim 64 was rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. This rejection has been rendered moot by the cancellation of the claim without prejudice.

Claim objection

Claim 68 was objected to as being a substantial duplicate. Applicants have corrected the dependency of the claim as provided above, and respectfully submit that this objection may be properly withdrawn.

Alleged issues under 35 U.S.C. §112, First Paragraph

Pending claims 66-85 were rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the enablement requirement. Applicants have carefully reviewed this rejection and respectfully traverse because no *prima facie* case has been presented. Applicants submit that the requirements of *In re Wands* have not been met and that proper consideration of the scope of the guidance provided in the instant application illustrates how the standard cannot be met to establish a *prima facie* case of non-enablement.

Appl. No. 09/844,281
Amdt. dated December 4, 2006
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1645

PATENT

As an initial matter, Applicants point out that the statement of rejection is in error in that Applicants do not characterize the disclosed EA1-specific antibodies as able to "bind other *Bacillus* organisms such as to the OlpA polypeptide of *B. licheniformis*." Instead, Applicants had pointed out that the polyclonal antibodies of the asserted Mesnage et al. document would be expected to bind to the OlpA polypeptide of *B. licheniformis*.

Turning to the inadequacies of this rejection, the standards provided by *In re Wands* are well settled and discussed at MPEP 2164.01(a). The statement of the rejection does not apply the factors to arrive at the assertion of non-enablement. Instead, the rejection appears to summarily require a deposit of antibodies. For example, there is no demonstration of undue unpredictability to produce additional antibodies for use in the claimed invention. Similarly, there is no demonstration of an undue amount of experimentation necessary to make and use the claimed invention. Additionally, there was no consideration of the amount and nature of the guidance provided by the disclosure and the existence of working examples.

Applicants point out that the specification of the instant application includes the Examples section, which begins on page 10 with a description of the immunization protocols that were used. The immunization protocol includes administration of spores of *B. thuringiensis* prior to fusion of antibody-producing B-cells from the immunized mice to produce hybridoma cells. The result of this protocol was the production of hybridoma cells that produced monoclonal antibodies that specifically bind spores or vegetative cells of *B. anthracis* relative to the spores or vegetative cells of *B. thuringiensis* as well as other species, such as *B. cereus*, *B. globigii*, and *B. licheniformis*. This is shown in the data included in the Examples section.

Therefore, and contrary to the statement of the rejection, the instant application provides a detailed protocol for preparing monoclonal antibodies that are representative of the claimed invention across the scope of the claims. Factually, the detailed protocol provides a means to produce *anthracis*-specific monoclonal antibodies without undue levels of unpredictability or undue amounts of experimentation. The instant rejection fails to provide any reason why this level and quantity of guidance is insufficient to enable the claimed invention. In light of this failure, Applicants submit that no *prima facie* case of non-enablement has been

Appl. No. 09/844,281
Amdt. dated December 4, 2006
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1645

PATENT

demonstrated and no such case can be presented. Accordingly, this rejection may be properly withdrawn.

Alleged issues under 35 U.S.C. §102 and 103(a)

Pending claims 66-85 were not rejected under 35 U.S.C. §102 or 103 in light of Mesnage et al. alone or in combination with any other reference. Thus the claims are believed to be free of issues based on Mesnage et al.

Pending claims 66, 68, and 79-85 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ezzell Jr. et al. Applicants have carefully reviewed this rejection and respectfully traverse because no *prima facie* case has been presented. Applicants submit that the factually, Ezzell Jr. et al. do not disclose or suggest a monoclonal antibody and so cannot anticipate the claims.

As an initial matter, Applicants believe that the non-inclusion of claims 67 and 69-78 reflects that these claims are free of issues based on Ezzell Jr. et al. Confirmation of this understanding in the next Office Communication is respectfully requested.

An essential component of a *prima facie* case of anticipation is that all features of a claimed invention must be disclosed in a single document. See MPEP 2131 and the cases cited therein.

But the instant rejection fails to meet this requirement because Ezzell et al. do not disclose or suggest a monoclonal antibody, or a fragment thereof, that "specifically binds spores or vegetative cells of *B. anthracis* relative to the spores or vegetative cells of *B. thuringiensis*, *B. cereus*, *B. globigii*, and *B. licheniformis*" as required by the rejected claims.

Based on the foregoing, Applicants respectfully submit that no *prima facie* case of anticipation exists and the instant rejection may be properly withdrawn.

RECEIVED
CENTRAL FAX CENTER

DEC 04 2006

PATENT

Appl. No. 09/844,281
Amdt. dated December 4, 2006
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1645

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,



Kawai Lau, Ph.D.
Reg. No. 44,461

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 858-350-6100
Fax: 415-576-0300
KL:ps
60891714 v1